

**Table 1: Published Clinical Trials on SNS, by Type of Indication**

<b>•</b>	<b>Schmidt 1999</b>	<b>Hassouna 2000</b>	<b>Jonas 2001</b>
<b>Indication</b>	Urge incontinence	Urgency-frequency syndrome	Urinary retention
<b>Type of Study Design</b>	Randomized, non-blinded	(Same as Schmidt 1999)	(Same as Schmidt 1999)
<b>Number of Centers</b>	16	12	13
<b>Consecutive Patients?</b>	No	No	No
<b>Total Eligible Patients, Prior to Test Stimulation</b>	155: 81%F, 19% M	Not Specified	177: 74% F, 26% M (42.9 +/- 12.7 years)
<b>Total Patients Randomized</b>	98: 52 Test, 46 Control	51: 25 Test, 26 Control 90% F, 10% M (39.0 +/- 11.8 years)	68: 37 Test, 31 Control
<b>Characteristics: Test vs. Control Group</b>	No matching performed in this clinical trial	No matching performed in this clinical trial	No matching performed in this clinical trial
<b>Inclusion Criteria</b>	(a) Age greater than 16; (b) Refractory to standard medical therapy; (c) 100 ml bladder capacity with normal upper urinary tract; (d) Good surgical candidate; and (e) Able to complete study documentation and return for follow-up study	(Same as Schmidt 1999)	(Same as Schmidt 1999)
<b>Exclusion Criteria</b>	(a) Neurological conditions (multiple sclerosis, diabetes with peripheral nerve involvement, spinal cord injury, stroke); (b) Stress UI; and (c) Primary pelvic pain	(Same as Schmidt 1999)	(Same as Schmidt 1999, with additional note that bladder outlet obstruction was excluded per discussion with one of study authors)
<b>Drop-Out Rate @</b>	34.6% in test arm	0% in test arm and	21.6% in test arm and

<b>6 Mo.</b>	and 8.7% in control arm	3.8% in control arm	29.0% in control arm
<b>Adjustment for Drop-Outs?</b>	Yes - Via sequential data analysis	Not Applicable	Not Specified
<b>Results @ 6 Mo. for Test Group Compared to Controls: Voiding Diary, Quality-of-Life (QOL) Instrument and Urodynamic Testing</b>	(a) Significant decrease ( $p<0.0001$ ) for incontinent episodes per day, severity rank of incontinence and replacement pads per day; (b) Significantly favorable perceptions on SF-36 Health Survey ( $p=0.0008$ ) and (c) No adverse urodynamic function	(a) Significant ( $p<0.0001$ ) decrease in number of voids per day; (b) Significant ( $p=0.01$ ) increase in volume voided per void; (c) Significantly reduced degree of urgency prior to voiding ( $p=0.01$ ); (d) Significant improvement (at least $p=0.01$ ) in 7/8 QOL parameters) and (e) No adverse urodynamic function	(a) Significant reduction in catheter volume per catheterization ( $p<0.0001$ ); (b) Significant decrease ( $p<0.0001$ ) in number of catheterizations per day, total catheter volume per day and maximum catheter volume; (c) Significant increase in number of voids per day ( $p=0.002$ ) and total volume voided per day ( $p<0.0001$ ) and (d) No adverse urodynamic function
<b>Duration of Results</b>	Up to 18 months, for single-armed group after crossover occurred at 6 months	At 12 and 24 months, for single-armed group after crossover occurred at 6 months	Up to 18 months, for single-armed group after crossover occurred at 6 months